

FDA Issues Mentor 'Approvable Letter,' Opens Door for Silicone Breast Implant Resale

8 August 2005

[Device & Diagnostic Letter](#)

Vol. 32, No. 31

Copyright (c) 2005 Washington Business Information, Inc.

Silicone gel-filled breast implants came closer to being marketed again in the U.S. late last month when implant manufacturer Mentor announced it had received an "approvable letter" from the FDA for its MemoryGel implant. Such a letter is an important step in a process that could ultimately bring the controversial **silicone gel-filled breast implants** back to the U.S. marketplace after a 13-year absence.

Santa Barbara, Calif.-based Mentor was notified by the FDA that its premarket approval (PMA) application for its MemoryGel **breast implants** was "approvable with conditions." The agency's letter stipulates a number of conditions the company must satisfy in order to receive FDA approval to market and sell its gel-filled implants within the U.S.

"We will continue working with the FDA to address the approval conditions," stated Mentor President and CEO Joshua Levine during the company's conference call last week. Levine went on to say that since the final decision ultimately rests with the FDA, Mentor said it would be "imprudent to speculate on the outcome or the timing of a decision."

Mentor's MemoryGel silicone **breast implants** consist of a cohesive gel formulation to help ensure the gel acts as a unit rather than as a liquid.

In the event of a rupture, the "sticking-together" nature of the gel could help prevent migration of the substance into the body, said Mentor.

Low Rupture Data Catalyst for Approval

In April, the FDA's General and Plastic Surgery Devices Panel voted 7-2 in favor of recommending approval for Mentor's **silicone gel** implant PMA after hearing research stating that roughly 1 percent of the company's implants had ruptured over three years' time.

The data provided by the company indicated that only 1.4 percent of women with implants experienced a rupture, and there were no indications of adverse effects in any of those events (D&DL, April 18, Page 1).

The panel did, however, call for strict conditions to be attached to its recommendation, including: 1) requiring prospective patients to sign consent forms acknowledging implant risks, including the fact that they ultimately may

break and require removal or replacement; 2) opening a registry to track how patients fare long-term; and 3) continuing more formal studies to discover implants' rupture rates 10 years post-implantation.

Mentor, who is not divulging any specific information contained in its approvable letter, has said the FDA's conditions are "generally consistent" with those made by the April panel. The company says it maintains high hopes for final FDA approval.

"We believe that our data significantly differentiated our PMA and established a level of quality and science that supports full approval," Levine said.

Inamed, a manufacturer that is also seeking FDA approval for its own **silicone gel**-filled breast implant, also weighed in on Mentor's approvable letter. **Inamed** said it viewed the news "as positive for the industry, physicians and their patients." The same panel that recommended Mentor's PMA for approval voted 5-4 against approving **Inamed**'s PMA for its similar device, citing safety issues. **Inamed** has recently revised its PMA to provide the FDA longer-term rupture data (D&DL, Aug. 1, Page 9).

Several parties remained concerned **silicone gel**-filled **breast implants** could be more trouble than they are worth.

A number of women's organizations and a group of women senators have expressed their displeasure regarding the possibility that these products will soon make their way back into the U.S. marketplace.

Implant Sales Back Strong Earnings for Mentor

Mentor's success is reflected in its most recent earnings statement. It reported a 27 percent increase in net income for its fiscal 2006 first quarter to \$22.5 million, or 47 cents per share, from \$17.7 million, or 37 cents per share, from fiscal 2005's first quarter.

The company's earnings increase was backed by strong sales, which specifically showed an 11 percent growth over 2005's first quarter, from \$122.4 million to \$135.3 million.

Although it also manufactures a number of additional products -- such as those for its surgical urology division -- Mentor's aesthetics business accounted for more than half of its total sales for this quarter. Mentor's aesthetics sales were \$74.1 million, up 13 percent from such sales in fiscal 2005's first quarter.

Mentor's breast aesthetics unit made up a large part of its overall aesthetics division's sales. Implant sales were \$64.8 million, up 13 percent from the prior year.

Upon final FDA approval, Mentor's breast aesthetics division alone could account for much of the company's overall sales.

Mentor says it expects it will finish the year at the "high end" of its earnings per share guidance range of \$1.60 to \$1.65, boosted by the company's projected healthy earnings in 2006's first fiscal quarter. However, Levine stressed that this earnings estimate "does not include the impact of a potential full FDA approval for [its] **silicone gel PMA**." -- Dennis Ciszkeski (mailto:dciszkeski@fdanews.com)

Silicone Gel Breast Implants in America: A Timeline

1962

Silicone gel-filled breast implants become available for the first time

on the U.S. market.

1976

Under the Medical Device Amendment -- an amendment to the Federal Food, Drug, and Cosmetic Act -- the FDA is given authority to regulate medical devices. Due to a subsequently huge regulatory backlog, **silicone gel breast implants** remain on the market while awaiting review.

1988

The FDA classifies **silicone gel breast implants** as Class III devices.

Manufacturers are required to submit safety information to the FDA.

1991

The FDA concludes that its safety data about **breast implants** do not prove that the devices are safe nor harmful. Manufacturers are told to submit additional data.

1992

The FDA restricts the use of **silicone gel-filled breast implants**, citing safety concerns about possible rupture and harmful effects if **silicone**

gel were to leak into patients' bodies. Silicone implants are restricted for use by patients undergoing **breast reconstruction** and by patients enrolled in clinical studies testing the implants' safety and effectiveness.

1995

Dow Corning, a manufacturer of **silicone gel breast implants** since the mid-1960s, files for Chapter 11 after numerous implant lawsuits were brought against the company dating from 1984.

1999

The Institute of Medicine releases a report saying that while **silicone gel breast implants** may cause hardening or scarring of breast tissue, they do not cause any major diseases.

2003

The FDA's General and Plastic Surgery Advisory Panel votes 9-6 to recommend approval of **Inamed's** premarket approval (PMA) application for its **silicone gel-filled** implants, with certain conditions.

2004

January -- The FDA sends **Inamed** a "not approved" letter for its silicone implant PMA application and requests additional data for further review.

December -- The FDA notifies **Inamed** and Mentor that it will review premarket approval applications submitted by both companies for their respective **silicone gel** implants.

2005

April -- The FDA's General and Plastic Surgery Devices Panel votes 7-2 in favor of Mentor's implant application. Conversely, the panel voted 5-4 a day earlier against recommending rival **Inamed's** application.

July -- Mentor receives an FDA "approvable letter" for its MemoryGel silicone implants.

Release date: Aug. 8, 2005